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REMARKS

This application is a continuation of serial no. 09/866,443. Claims 1-16 were present in the application when filed. In response to an Office Action dated April 25, 2005, claim 1 was amended. Claims 1-16 remain pending in the application.

Rejection under 35 U.S.C. §102

Claims 1 and 7-16 are rejected under 35 U.S.C. §102(b) as being anticipated by Oldroyd et al. (*Aust J. Agric Res*, 1989, 40(3), p. 691-698.) According to the Office Action, the rejection was on the grounds that Oldroyd et al. teach that honeybee colonies were treated with various oxytetracycline hydrochloride (OTC) preparations at the same time of inoculation with *Bacillus larvae* spores, thereby anticipating a composition as claimed by Applicants. The Office Action further states that “Oldroyd teaches a composition comprising *Bacillus larvae*...that were American Foubrood (AFB) disease-free at the time of sampling and did not subsequently develop disease signs.” From this, the Office Action concludes that Oldroyd teaches Applicants’ claimed composition. Applicants respectfully submit that a proper reading of Oldroyd makes it clear that *B. larvae* is *not*, as the Office Action maintains, non-pathogenic to bees. Oldroyd, therefore, cannot anticipate the present invention.

Independent claim 1 of the instant application, as previously presented, recites a composition *for the treatment or prophylaxis of a bee disease*, the composition comprising: a) an inoculum containing one or more microorganisms *that are non-pathogenic to bees* for producing a microflora *having therapeutic or prophylactic efficacy against the bee disease*; and b) an apicultural delivery vehicle for delivering the inoculum to a component of a bee hive, or to a bee colony that is susceptible to or infected with the bee disease, whereby *a remedial and/or protective microflora is established* within the hive or the bee colony. Thus, a primary feature of the claimed composition is an inoculum of one or more microorganisms that are non-pathogenic to bees.

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A proper reading of Oldroyd would not lead one of skill in the art to conclude that *B. larvae* is a non-pathogenic organism. In direct contrast, Oldroyd teaches that *Bacillus larvae* is a pathogenic organism, administered to induce disease. Oldroyd presents the results of a study of the effect of oxytetracycline hydrochloride treatment on American foulbrood. In these studies, honeybee colonies were treated with oxytetracycline hydrochloride preparations at the time that the colony was inoculated with *Bacillus larvae* spores to induce the disease or after American foulbrood disease signs had developed. Not surprisingly, Oldroyd (abstract) states that *B. larvae* was subsequently cultured from adult bee samples from colonies that did not develop disease signs. These colonies, however, were treated with OTC. Oldroyd does not suggest that these colonies are disease free subsequent to inoculation with *B. larvae* because is not a pathogen; rather, Oldroyd concludes that these results show that recommended treatments for European foulbrood (EFB), i.e., treatment with OTC, essentially suppress signs of AFB disease.

The relevant portion of Oldroyd appears on page 693 and reads as follows:

“Experiment 1: Effects of OTC as a Preventative of AFB Disease

All control colonies [emphasis added] inoculated with *B. larvae* spores developed disease signs within 40 days (Fig.1). OTC treatment at the time of inoculation prevented the development of disease signs for 58 days in one hive, 291 days in another hive and two other colonies became diseased in mid-summer, more than 1 year after their inoculation with *B. larvae* spores. *AFB disease was prevented by OTC treatment at the time of inoculation in 1 colony only* (Fig.1)."

Thus, *all of the control colonies*, that is, those receiving *B. larvae* spores in the absence of OTC, developed disease signs. Of the colonies inoculated with *B. larvae* and treated with OTC, *only one* colony was disease-free at the time of sampling. The absence of signs of disease in this single colony does not indicate that *B. larvae* is non-pathogenic, rather, it is due to the fact that the colony was successfully treated with OTC, an antibacterial agent effective against *B. larvae*.

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Applicant does not disagree with the definition of non-pathogenic put forth in the Office Action. Applicants do, however, dispute the Office Action's characterization of *B. larvae* as a non-pathogenic organism rather than a pathogenic one (See Annex A for the definition of pathogen.) There is no evidence in the prior art to suggest that *Bacillus larvae* is a non-pathogenic strain of bacteria. Rather, the relevant literature, including Oldroyd, teaches that American foulbrood (AFB) is caused by *B. larvae* (now known as *Paenibacillus larvae* subsp. *larvae*). The literature also teaches that oxytetracycline hydrochloride (OTC) therapy is commonly used to control American foulbrood (AFB). In support of this position, Applicants submit three additional documents, labeled Annex B-D. Annex B, an abstract from a report by Genersch et al. entitled "Strain- and Genotype-Specific Differences in Virulence of *Paenibacillus larvae* subsp. *larvae*, a Bacterial Pathogen Causing American Foulbrood Disease in Honeybees," unequivocally identifies *Paenibacillus larvae* subsp. *larvae* as the causative agent of American foulbrood disease. Annex C, the abstract from a report from Rural Industries Research and Development Corporation of the Australian government, on oxytetracycline sensitivity of *Paenibacillus larvae* subsp. *larvae* isolates states that American foulbrood (AFB) is caused by *Paenibacillus larvae* subsp. *larvae* and establishes that *P. larvae* subsp. *larvae* isolated from Australian sources are very sensitive to OTC. Lastly, an entry from DSMZ, Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH, clearly identifies *Paenibacillus larvae* subsp. *larvae* (synonym *Bacillus larvae*) as an animal pathogen (Annex D).

It necessarily follows that, inoculation of a bee colony with *B. larvae* would not be able to produce a *microflora having therapeutic or prophylactic efficacy against the bee disease*, as recited by independent claim 1. Indeed, Oldroyd does not teach the establishment of a protective microflora within the hive or bee colony.

Treatment or prevention of bee disease by Applicant's claimed composition is achieved either by the non-pathogenic microorganism producing an antibiotic against a pathogenic microorganism or by a population of the non-pathogenic microorganism competing with

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pathogenic microorganisms and preventing infection thereby. This is discussed on page 3 of the description.

Lastly, it is well established that a preamble that "breathes life and meaning into the claim is a necessary limitation to them." In the present case, the claimed composition is for the treatment or prophylaxis of a bee disease. In view of the clear teachings of Oldroyd that colonies were inoculated with *B. larvae* for the purpose of inducing foulbrood disease, one of skill in the art would appreciate that Oldroyd cannot anticipate Applicants claimed composition for the treatment of the disease.

Having clearly established that *Bacillus larvae* (now known as *Paenibacillus larvae* subsp. *larvae*) is a pathogenic rather than a non-pathogenic organism, Applicants' respectfully submit that the claimed composition comprising an inoculum of non-pathogenic microorganism is in stark contrast to the compositions of the cited references which contain an inoculum of the pathogen for inducing disease which applicants' claimed composition seeks to treat or prevent. Therefore, Oldroyd et al teaches inoculation with a microorganism that is pathogenic to bees and, as such, Oldroyd cannot anticipate Applicants' invention.

Claims 1 and 7-16 are further rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious by Hoopingarner et al. (*American Bee Journal*, 1988, Vol. 128, No. 2, p. 120-121).

Hoopingarner, like Oldroyd, teaches inoculation with *B. larvae* pathogen for the purpose of inducing American foulbrood disease to evaluate the effectiveness of three terramycin formulations on that disease.

The relevant portion of Hoopingarner appears on page 120 and reads as follows:
"Three weeks after the nucs were established, they were inoculated with AFB [emphasis added] by spraying them with syrup containing a heavy concentration of *B. larvae* spores.

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After four weeks to allow the disease to become established, the treatment each nuc was to receive was chosen randomly."

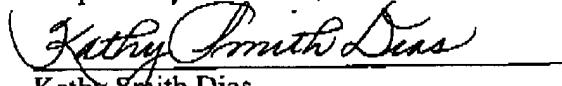
For the reasons given above with respect to the teachings of Oldroyd, Hoopingarner does not teach or fairly suggest a composition comprising an inoculum of non-pathogenic microorganisms for the prevention of *B. larvae* induced foulbrood disease. Furthermore, the teachings of Hoopingarner do not compensate for the shortcomings of Oldroyd. The combination of the references does not teach Applicants' claimed composition.

Withdrawal of the rejection under 35 U.S.C. §§ 102/103 is respectfully requested.

For the foregoing reasons, the claims are believed in condition for allowance and such action is respectfully requested. The dependent claims are believed allowable for the same reasons as the independent claims from which they ultimately depend, as well as for their additional limitations.

Should the Examiner require clarification of any of the above, she is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,



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ANNEX A

patch board

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together temporarily by means of a patch board. 20. (usually foll. by *through*) to connect (a telephone call) by means of a patch board. 21. Computer technician to correct or improve (a program) by adding a small set of instructions. [C16 *pacche*, perhaps from French *poché* *PIECE*] —'patchable' adj. —'patcher' n.

patch board or **panel** n. a device with a large number of sockets into which electrical plugs can be inserted to form many different temporary circuits; used in telephone exchanges, computer systems, etc. Also called *patchboard*.

patchouli, **patchouli**, or **patchouly** (pach'ü, pôchü'lë) n. 1. any of several Asiatic trees of the genus *Pogostemon*, the leaves of which yield a heavy fragrant oil. 2. the perfume made from this oil. [C16: from Tamil *paččai*, from *pačču* green + *čai* leaf]

patch pocket n. a pocket on the outside of a garment.

patch quilt n. Irish. a patchwork quilt.

patch test n. Med. a test to detect an allergic reaction by applying small amounts of a suspected substance to the skin and then examining the area for signs of irritation.

patchwork (pach'wôrk) n. 1. needlework done by sewing pieces of different materials together. 2. something, such as a theory, made up of various parts: a patchwork of cribbed ideas.

patchy ('pach'ë) adj. 1. irregular in quality, occurrence, intensity, etc.: a patchy essay. 2. having or forming patches. —'patchily' adv. —'patchiness' n.

paté abrégé for *patented*.

paté (pät) n. 1. the head, esp. with reference to baldness or (in facetious use) intelligence. [C14: of unknown origin]

paté (pä'tär) French *pâté*) n. 1. a spread of very finely minced liver, poultry, etc., served usually as an hors d'œuvre. 2. a savoury pâté of meat or fish. [from French: *PASTE*]

paté de foie gras (päté dô fwa grä) n. pl. *pâtés de foie gras* (päté dô fwa grä) a smooth rich pâté made from the liver of a specially fattened goose, considered a great delicacy. [French: *pâté* of fat liver]

patella (pä'tälä) n., pl. -lae (-lä). 1. Anatomy. a small flat triangular bone in front of and protecting the knee joint. Nontechnical name: knee-cap. 2. *Biology*. a cuplike structure, such as the spore-producing body of certain ascomycetous fungi. 3. Archaeol. a small pan. [C17: from Latin, from *patella* shallow pan] —'patellar' adj.

patellite (pä'tälit, -lälit) adj. having the shape of a patella. Also: *patelline* (pä'tälin, -lälin).

paten ('pätñ) patin, or **patine** ('pätñ) n. a plate, usually made of silver or gold, esp. the plate on which the bread is placed in the Eucharist. [C15: from Old French *patene*, from Medieval Latin, from Latin *patina* pan]

patency ('peñ'ëns) n. 1. the condition of being obvious. 2. the state of a bodily passage, duct, etc., of being open or unobstructed. 3. Phonetics. the degree to which the vocal tract remains unobstructed in the articulation of a speech sound. See also closure (sense 6).

Patenier n. Joachim. See (Joachim) *Patinier*.

patent ('peñ'ënt, 'peñ'ënt) n. 1. a government grant to an inventor assuring him the sole right to make, use, and sell his invention for a limited period. 2. a document conveying such a grant. 2. an invention, privilege, etc., protected by a patent. 3. a. an official document granting a right. b. any right granted by such a document. 4. (in the U.S.) a. a grant by the government of title to public lands. b. the instrument by which such a grant is granted. c. the land so granted. 5. a sign that one possesses a certain quality. ~adj. 6. open or available for inspection (esp. in the phrases *letters patent*, *patent writ*). 7. ('peñ'ënt). obvious: their scorn was patent to everyone. 8. concerning protection, appointment, etc., of or by a patent or patents. 9. proprietary. 10. (esp. of a bodily passage or duct) being open or unobstructed. 11. *Biology*. spreading out widely: *patent branches*. 12. (of plate glass) ground and polished on both sides. ~vb. (tr.) 13. to obtain a patent for. 14. (in the U.S.) to grant (public land or mineral rights) by a patent. 15. *Metallurgy*. to heat (a metal) above transformation temperature and cool it at a rate that allows cold working. [C14: via Old French from Latin *patere* to lie open; n. use, short for *letters patent*, from Medieval Latin *litterae patentes* letters lying open (to public inspection)] —'patentable' adj. —'patentability' n.

► Usage. The pronunciation "peñ'ënt" is heard in *letters patent* and *Patent Office* and is the usual U.S. pronunciation for all senses. In Britain "peñ'ënt" is sometimes heard for senses 1, 2 and 3, but "peñ'ëns" is commoner and is regularly used in collocations like *patent leather*.

patented ('peñ'ënt, 'peñ'ënt) n. a person, group, company, etc., that has been granted a patent.

patent fastener n. (in Ireland) another name for *press stud*.

patent leather n. leather or imitation leather processed with lacquer to give a hard glossy surface.

patent log n. *Nautical*. any of several mechanical devices for measuring the speed of a vessel and the distance travelled, consisting typically of a trailing rotor that registers its rotations on a meter. Compare *chip log*.

patently ('peñ'ëntli) adv. obviously: he was patently bored.

patent medicine n. medicine, usually of low potency, protected by a patent and available without a doctor's prescription.

Patent Office ('peñ'ëntfis) n. a government department that issues patents. Abbrev.: *Pat. Off.*

patentor ('peñ'ëntör, 'peñ'ëntör) n. a person who or official body that grants a patent or patents.

patent right n. the exclusive right granted by a patent.

Patent Rolls pl. n. (in Britain) the register of patents issued.

patent still n. a type of still in which the distillation is continuous. (so called because a still of this type was patented in 1830)

paté ('peñ) n. Brit. a public school slang word for father; now chiefly used facetiously. [from Latin]

pathology

pa

Paté ('peñtö) n. Walter (Horatio), 1839-94, English essayist and critic, noted for his prose style and his advocacy of the "love of art for its own sake". His works include the philosophical romance *Marius the Epicurean* (1855), *Studies in the History of the Renaissance* (1873), and *Imaginary Portraits* (1887).

paternalis (peñ'terënlës) n., pl. *patresfamilias* (peñ'terënlës'fëmiliës). 1. the male head of a household. 2. Roman law. a. the head of a household having authority over its members. b. the parental or other authority of another person. [Latin: father of the family]

paternal (peñ'terënlë) adj. 1. relating to or characteristic of a father, esp. in showing affection, encouragement, etc.: fatherly. 2. (pro)nominally related through the father: his paternal grandfather. 3. inherited or derived from the male parent. [C17: from Late Latin *paternalis*, from Latin *paternus* father] —'paternally' adv.

paternalism (peñ'terënlëzëm) n. the attitude or policy of a government or other authority that manages the affairs of a country, company, community, etc., in the manner of a father, esp. in usurping individual responsibility and the liberty of choice. —'paternalist' n., adj. —'paternalistic' adj. —'paternalistically' adv.

paternity (peñ'terënlë) n. 1. a. the fact or state of being a father. b. (as modifier): a paternity suit was filed against the man. 2. descent or derivation from a father. 3. authorship or origin: the paternity of the theory is disputed. [C18: from Late Latin *paternitas*, from Latin *pater* father]

paternity suit n. Law. the U.S. (and in Britain a nontechnical) term for affiliation proceedings.

paternoster (peñ'terëstör) n. 1. R.C. Church. the beads at the ends of each decade of the rosary marking the points at which the Paternoster is recited. 2. any fixed form of words used as a prayer or charm. 3. Also called *paternoster line*, a type of fishing tackle in which short lines and hooks are attached at intervals to the main line. 4. a type of sit in which platforms are attached to continuous chains. The lift does not stop at each floor, but passengers enter while it is moving. [Latin, literally: our father (from the opening of the Lord's Prayer)]

Paternoster (peñ'terëstör) n. (sometimes not cap.) R.C. Church. 1. the Lord's Prayer, esp. in Latin. 2. the recital of this as an act of devotion. [see *PATEROSTER*]

Paterson ('peñsërn) n. a. a city in NE New Jersey; settled by the Dutch in the late 17th century. Pop.: 139,180 (1980 est.).

Paterson ('peñsërn) n. 1. Andrew Barton, known as Banjo Paterson, 1864-1941, Australian poet. His works include "Waltzing Matilda" and "The Man from Snowy River". 2. William, 1659-1719, Scottish merchant and banker; founded the Bank of England (1694).

Paterson's curse n. an Australian name for viper's bugloss.

path (päth) n. pl. *paths* (päþëz). 1. a road or way, esp. a narrow trodden track. 2. a surfaced walk, as through a garden. 3. the course or direction in which something moves: the path of a whirlwind. 4. a course of conduct: the path of virtue. [Old English *path*; related to Old High German, German *pfad*] —'pathless' adj.

path (päth) abbr. for: 1. pathological. 2. pathology.

path n. combining form. 1. denoting a person suffering from a specified disease or disorder: *neuropath*. 2. denoting a practitioner or of a particular method of treatment: *osteopath*. [back formation from *PATHY*]

Pathan (peñ'tän) n. a member of the Pashto-speaking people of Afghanistan, NW Pakistan, and elsewhere, most of whom are Muslim in religion. [C17: from Hindi]

pathetic (peñ'ëtik) adj. 1. evoking or expressing pity, sympathy, etc. 2. distressingly inadequate: the old man sat huddled in front of a pathetic fire. 3. Brit. Informal. ludicrously or comically uninteresting or worthless: the standard of goalkeeping in amateur football today is pathetic. 4. Obsolete or of or affecting the feelings. —pl. n. 5. pathetic sentiments. [C16: from French *pathétique*, via Late Latin from Greek *pathetikos* sensitive, from *pathos* suffering; see *PATHOS*] —'pathetically' adv.

pathetic fallacy n. (in literature) the presentation of inanimate objects in nature as possessing human feelings.

pathfinder ('peñ'ëfëndër) n. 1. a person who makes or finds a way, esp. through unexplored areas or fields of knowledge. 2. an aerial or parachutist who indicates a target area by dropping flares, etc. 3. a radar device used for navigation or homing onto a target. —'pathfinding' n.

pathic ('peñ'ëtik) n. 1. a catastrophe. 2. a person who suffers, victim. ~adj. 3. or of relating to a catastrophe. 4. or of relating to suffering. [C17: via Latin from Greek *pathikos* passive; see *PATHOS*]

patho- or **before a vowel** **path-** combining form: disease: *pathogen*, *pathology*, from Greek *pathos* suffering; see *PATHOS*

pathogen ('peñ'ëgëñ) or **pathogene** ('peñ'ëgëñ) n. any agent that can cause disease.

pathogenesis ('peñ'ëgëñsës) or **pathogeny** ('peñ'ëgëñsë) n. the origin, development, and resultant effects of a disease. —'pathogenetic' (peñ'ëgëñtik) adj.

pathogenic ('peñ'ëgëñtik) adj. able to cause or produce disease; pathogenic bacteria.

pathognomonic ('peñ'ëgëñmënik) adj. Pathol. characteristic or indicative of a particular disease. [C17: from Greek *pathognomikos* expert in judging illness, from *PATEO* + *gnomikos* judicious; —pathognomically adv.]

pathognomy ('peñ'ëgëñmë) n. study or knowledge of the passions of emotions or their manifestations. [C18: from *PATHO* + *gnomé*, as in *PHYSIOMÉTRY*]

pathol. abbr. for: 1. pathological. 2. pathology.

pathological ('peñ'ëlodjiklë) or (less commonly) **pathologic** ('peñ'ëlodjik) adj. 1. or of relating to pathology. 2. relating to, involving, or caused by disease. 3. Informal. compulsively motivated: a pathological liar. —'pathologically' adv.

pathology ('peñ'ëlodjë) n., pl. -gies. 1. the branch of medicine

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0099-2240/05/\$08.00+0 doi:10.1128/AEM.71.11.7551-7555.2005
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ANNEX B

SHORT REPORT

Strain- and Genotype-Specific Differences in Virulence of *Paenibacillus larvae* subsp. *larvae*, a Bacterial Pathogen Causing American Foulbrood Disease in Honeybees

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Virulence variations of *Paenibacillus larvae* subsp. *larvae*, the causative agent of American foulbrood disease of honeybees, were investigated by analysis of 16 field isolates of this pathogen, belonging to three previously characterized genotypes, as well as the type strain (ATCC 9545) of *P. larvae* subsp. *larvae*, with exposure bioassays. We demonstrated that the strain-specific 50% lethal concentrations varied within an order of magnitude and that differences in amount of time for the pathogen to kill 100% of the infected hosts (LT_{100}) correlated with genotype. One genotype killed rather quickly, with a mean LT_{100} of 7.8 ± 1.7 days postinfection, while the other genotypes acted more slowly, with mean LT_{100} s of 11.2 ± 0.8 and 11.6 ± 0.6 days postinfection.

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ANNEX C



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Summary of full report

Oxytetracycline sensitivity of *Paenibacillus larvae*. subsp. *larvae* isolates

by Michael Hornitzky

January 2005

RIRDC Publication No 05/021 RIRDC Project No DAN-219A

Executive summary

American foulbrood (AFB), caused by *Paenibacillus larvae* subsp. *larvae*, is considered to be the most important bacterial disease of honey bees in Australia. In many countries oxytetracycline hydrochloride (OTC) is used to treat the disease. On mainland Australia AFB is controlled by the incineration of infected hives or the irradiation of hive material from diseased hives. Tasmania is the only state which permits treatment with OTC.

In recent years OTC-resistant *P. l.* larvae have emerged in the United States of America, Canada and Argentina. There is no information on the OTC sensitivity of *P. l.* larvae in Australian bees and whether honey imported from overseas (Argentina) contains OTC-resistant *P. l.* larvae. This information is important as it has a bearing on future control options for bacterial honey bee diseases in Australia.

This study has demonstrated that *P. l.* larvae isolated from Australian sources are very sensitive to OTC and that no resistance to OTC appears to have developed over the past 15/16 years. Most isolates from imported honey had higher minimum inhibitory concentrations for OTC than Australian isolates but the difference was so minor that they would all still be considered to be very sensitive to OTC.

This indicates that honey imported from Argentina has not been a significant source of OTC-resistant *P. l.* larvae.

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ANNEX D

DSMZ - List of Microbial Species: *Paenibacillus larvae* subsp. *larvae* (Bacteria)

DSMZ

© by DSMZ-Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH, Braunschweig, Germany

Name	<i>Paenibacillus larvae</i> subsp. <i>larvae</i> (White 1906) Ash et al. 1994 emend. Heyndrickx et al. 1996 VP - see also <u>Bacterial Nomenclature Up-to-Date</u>
Synonym	<i>Bacillus larvae</i>
Restrictions	Animal pathogen, restricted distribution (F)
Strains	7030

DSMZ

Microorganisms